APR - 5 2001

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510(k) Summary

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

Daniel Hoefer
ARC Laser Corporation
2417 South 3850 West
Salt Lake City, UT 84104
(801) 972-1311, FAX (801) 972-5251

Name of Device:

Trade Name: Nuvlase 532 Medical Laser System

Common Name: Medical/surgical laser system

Classification name:
Laser system, powered, surgical

Product Code: GEX

Device Class: Class II

Predicate Devices:

Substantially equivalent, legally marketed devices include the HGM PC EDO (K921300), Laserscope Aura (K951034) and the Ceramoptec G15 (K002296).

Description of Device:

The **Nuvolase 532M Medical Laser System** is a class II device intended for use in ophthalmology, dermatology, and ENT. The treatment wavelength is 532 nm and the aiming beam is provided by a red diode laser. The laser can deliver up to 2.5 Watts of power in continous wave operation or pulsed operation.

User-controlled pulse duration settings range from 0.01 seconds to 1.0 seconds and continuous. The interval between pulses is also adjustable between 0.2 seconds and 1.0 seconds, or single pulse mode.

The system consists of a main laser module, a tethered control module, and a footswitch. A fiber port enables fiber optic delivery of the laser energy via several delivery options. The fiber port has sensors that automatically calibrate the laser power display according to the type of attachment.

The total weight of the system is 23 lb. (10 Kg.). The dimensions of the main module are 17 X 11 X 5 inches (43 X 28 X 13 cm). Electrical power is required is either 115 VAC or 208-240 VAC. Accessories available with the system include laser safety eyewear.

Intended Use:

Nuvolase 532 Medical Laser System is intended for use by a physician in ophthalmic, cutaneous, and ENT indications. When used with a slit lamp biomicroscope attachment it is intended for use in retinal and macular photocoagulation or trabeculoplasty. When used with an ophthalmic endoprobe attachment it is intended for endophotocoagulation. When used with the cutaneous focusing handpiece, it is intended for use in the treatment of vascular and pigmented cutaneous lesions. It also may be used with ENT endoprobes for incision, excision, coagulation, vaporization, and hemostasis.

Technological Characteristics/Device Comparison:

The Nuvolase 532 Medical Laser System is a continous wave frequency doubled Nd:YAG laser system. An Nd:YAG crystal is optically pumped by a diode laser, resulting in laser emission at 1064 nm. This laser output is coupled into a crystal that exhibits a non-linear optical response, resulting in emission at the first harmonic of the 1064 nm wavelength, 532 nm.

The green 532 nm wavelength is coupled into a fiber port, where it can be delivered to tissue by the various fiber optic delivery devices. Within the laser module housing are shutters and optical elements that allow the beam to be chopped or attenuated to produce the various power or fluence levels that optimize laser treatment.

Each of the predicate device is a class IV laser system producing green wavelength continuous wave or quasi-cw output, as is the Nuvolase 532. Each is intended for fiber optic delivery using various delivery devices specific to the intended use of the laser energy, as is the Nuvolase 532. Each predicate device enables the user to set the

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pulse duration and power levels for control of the delivered laser energy, as does the Nuvolase 532. Each device is intended for ophthalmic photocoagulation and/or treatment of vascular and pigmented cutaneous lesions and/or ENT usage for incision, excision, coagulation, vaporization and hemostasis.

The laser system construction, treatment wavelength, pulse duration control, delivery system(s), intended use, warnings and cautions, labelling, materials, method of manufacture, power source, and aiming method are all the same or equivalent.

Conclusion:

The Nuvolase 532 Medical Laser System does not raise new questions of safety and effectiveness and is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Mr. Daniel Hoefer
Regulatory Affairs
ARC Laser Corporation
2417 South 3850 West
Salt Lake City, Utah 84120

Re: K010046
Trade Name: Nuvolase 532 Medical Laser System
Regulatory Class: II
Product Code: GEX
Dated: January 4, 2001
Received: January 5, 2001

Dear Mr. Hoefer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010046

Device Name: NUVOLASE 532 MEDICAL LASER SYSTEM

Indications For Use:

OPHTHALMOLOGY:

Retinal and macular photocoagulation, endophotocoagulation, trabeculoplasty

DERMATOLOGY:

Treatment of vascular cutaneous lesions (angioma, hemangioma, telangiectasia) and pigmented cutaneous lesions (lentigines, café au lait, nevi)

ENT:

Incision, excision, coagulation, vaporization, ablation and hemostasis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010046

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)